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PATENT
Docket No.: 026549-000100US
Client Ref. No.: 30836

TOWNSEND and TOWNSEND and CREW LLP

By: /Jo Ann Honcik Dallara/
Jo Ann Honcik Dallara

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Ronit Eisenberg et al.

Application No.: 10/009,809

Filed: April 26, 2002

For: CELL PENETRATING ANTI-
ALLERGIC PEPTIDES

Customer No.: 20350

Confirmation No.: 1519

Examiner: Dahle, Chun Wu

Before: Grimes, Adams, and Walsh;
Administrative Patent Judges

Technology Center: 1600
Art Unit: 1644

**REQUEST FOR REHEARING
UNDER 37 C.F.R. § 41.52**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Decision of April 26, 2010, and in accordance with the provisions of 37 C.F.R. § 41.52, appellants request rehearing in the above-captioned application.

The Panel was asked to review an obviousness rejection. Appellants believed that the Examiner ignored declaratory evidence of unpredictability and sought review of its sufficiency. It is respectfully submitted that the Board misunderstood the surprising feature when it concluded that appellants provided **inadequate** evidence of unpredictability regarding transport of proteins into cells. Predictability of protein transport was never at issue. *Biological activity after transport* was the issue presented by appellants for review.

Appellants regret the confusion and request a rehearing to either have the rejection reversed or to have an explanation of why the relevant evidence presented in the file history was inadequate to traverse the *prima facie* case of obviousness.

This invention provides for the fusion of a known biologically active protein to a known cell penetrating peptide (CPP). The claims are limited to the use of Lin's CPP to transport Aridor's inhibitor peptide into mast cells to prevent the release of histamines that trigger an allergic response. The Panel in maintaining the rejection wrote on page 8 of its decision:

Appellants have not, however, adequately explained why the failure of the other signal peptides would have led a skilled worker to doubt **Lin's statement that the KFGF signal peptide directs importation of an attached peptide into cells.**

Importation or peptide transport was not at issue in this case. It is a predictable event. No evidence was provided on this point.

The issue before the Board was whether the reasons provided by the declarants regarding the **unpredictability of biological activity** after importation was adequate to rebut the *prima facie* case of obviousness. Appellants wrote on page 7 of the appellants' brief:

The fact that only one of the four CPPs tested successfully delivered a biologically active inhibitor was a surprise.

Again, predictability of delivery was not at issue. Predictability of biological activity once imported into the cell was the technical issue before the Board and the sufficiency of the appellants' evidence of unpredictability was the legal issue.

If the Board believes that retention of biological activity is presumptive and implied by the prior art disclosing CPPs, there is no evidence of this in the record. None of the various references disclosing CPPs, including the

Lin reference, promise to retain biological activity of your transported peptide—they only promise importation across a cell membrane.

Once a fusion protein is delivered into a cell across its cell membrane, the cell can unpredictably take a host of actions to a foreign protein. As part of its natural defense mechanisms against pathogens and toxins, most actions will cause the intruder protein to be sequestered or degraded rendering it non-functional. As evidence of the unpredictability of biological activity after transport into a mast cell, appellants provided experimental evidence of the failure of various CPPs to retain the biological activity of Aridor's peptide (p. 7) and two expert declarants provided three objective reasons why retention of activity was unpredictable once a protein is transported into a cell by any CPP (p. 8)¹. Appellants then urged that it was surprising and unpredictable that Aridor's peptide retained biological activity when linked with Lin's CPP but not with other CPPs.

Appellants respectfully request reconsideration of the Board's decision to maintain the rejection. If the Board elects to maintain the rejection, appellants respectfully request clarification regarding why the Board believes that the experimental evidence and the two declarants' objective explanations, are, in combination, inadequate to rebut the *prima facie* case of obviousness.

Respectfully submitted,

/Kenneth A. Weber/

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¹ Pages refer to Appellants' Brief.

Ronit Eisenberg et al.
Appln.: 10/009,809
Response dated June 10, 2010
Reply to Decision of April 26, 2010

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